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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,229	10/02/2006	Eva Blychert	1103326-0902	7595

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PATENT DEPARTMENT
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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
11/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,229	BLYCHERT ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 18* is/are pending in the application.

4a) Of the above claim(s) *6,7 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 5, 8 - 13, 15 - 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/27/06, 2/27.06,11/15/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of starch the pharmaceutically acceptable thickener in the reply filed on August 15, 2008 is acknowledged. The traversal is on the grounds that a single general inventive concept is present in that an aqueous viscous medium in which the enteric coated pellets are suspended. Logic dictates that prior art against one species will also be material to the patentability of the other species.

This is not found persuasive because as Applicant has pointed out, under this general concept are two species – an aqueous viscous media and an aqueous liquid formed by dispersing a pharmaceutically acceptable thickener. The aqueous media need not contain a thickener and therefore the art applicable to one species does not necessarily read on the other species.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claim 1 is objected to because of the following informalities: it appears that a typographical error is present in line 5. The phrase "in the form of a multiple of enteric coated layered pellets" appears to contain an extra "a". Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 – 5, 8, 9, 12 and 15 – 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Olovson et al. (WO 94/25070).

Olovson et al. discloses a composition comprising a proton pump inhibitor and a gelling agent for the treatment of gastric acid related diseases (gastrointestinal disorders) in animals (abstract). Enteric coated, dry particles of the proton pump inhibitor are mixed with dry gelling agent(s) so that when water is added, a paste-like gel is formed (p 3, ln 4 – 13). Examples given for the active ingredient include omeprazole, lansoprazole amd pantoprazole (p 5). The volume administered to the patient is in the range of 5 – 50 mL (p 7, ln 27 – 28). In the examples (beginning on p 9), omeprazole enteric-coated pellets prepared according to US 4786505 are prepared. In example 2 (p 10), a solid composition comprising the enteric coated particles, xanthan gum and the flavoring agent citric acid are combined to form a solid composition. This forms a gel in a syringe when 10 mL of water is added.

Multiple enteric coated pellets of acid labile proton pump inhibitor and a thickener in a aqueous suspension are present in the composition of Olovson et al. The viscosity

of the final preparation and the size of the enteric coated pellets present in this formulation are not reported. In both the instant application and the cited prior art, the enteric coated pellets are made using a process in which a core containing the active ingredient is coated with separating layer(s) and an enteric coating layer. As the structural limitations of the ingredients in the composition and the method of making the pellets are similar, there is currently no evidence on the record to indicate that the pellet size viscosity limitations of the compositions prepared by Olovson et al. do not meet the size and viscosity limitations claimed by Applicant, It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 – 5, 8 – 9, 12, 13 and 15 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olovson et al. (WO 94/25070).

Olovson et al. discloses a composition comprising a proton pump inhibitor and a gelling agent for the treatment of gastric acid related diseases in animals (abstract). Enteric coated, dry particles of the proton pump inhibitor are mixed with dry gelling agent(s) so that when water is added, a paste-like gel is formed (p 3, ln 4 – 13). Other substances such as flavoring substances may be incorporated into the composition (p

7, ln 30 – 31). Examples given for the active ingredient include omeprazole, lansoprazole and pantoprazole (p 5). The volume administered to the patient is in the range of 5 – 50 mL (p 7, ln 27 – 28). In the examples (beginning on p 9), omeprazole enteric-coated pellets prepared according to US 4786505 are prepared. In example 2 (p 10), the enteric coated particles, xanthan gum and citric acid are combined to form a solid composition. This forms a gel in a syringe when 10 mL of water is added.

Olovson et al. does not disclose a proton pump inhibitor dosage of 1 - 100 mg.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to optimize the amount of proton pump inhibitor present in the composition disclosed by Olovson et al. based on the specific active ingredient being used, the severity of the condition of the patient and the dosing schedule (once or multiple times per day). One of ordinary skill would also optimize the amount of gelling agent, and thus the viscosity of the gel, to produce a solution that could be administered through the syringe. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success.

9. Claims 1 – 5, 8, 9, 12, 13 and 15 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olovson et al. in view of Calanchi et al. (US 6,261,602).

As discussed in greater detail above, Olovson et al. discloses compositions of enteric coated proton pump inhibitor particles, a gelling agent and optional flavoring components. The gelling agents exemplified include a variety of gums (xanthan, guar,

or locust bean), tragacanth and modified cellulose derivatives (p 3, ln 9 – 11). The solid composition is mixed with water in a syringe to form an aqueous gel.

Olovson et al. does not disclose the use of starch as a component of the composition.

Calanchi et al. discloses thickening agent which dissolve in water and increase the viscosity of the aqueous media such as water (col 3, ln 64 – col 4, ln 1). Examples given of thickening agents include xanthan gum, guar gum, tragacanth, karaya gum and modified corn starch (col 4, ln 1 – 8). Calanchi et al. also discloses that the desired particle size is between 250 μm and 850 μm (col 5, ln 47 – 49). A particle size above 850 μm increases the time required to obtain a solution with a viscosity that can keep the particles in solution while particles sizes below 200 μm can lead to lump formation (col 5, ln 49 – 54).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare and administer a suspension of enteric coated proton pump particles and a gelling agent as taught by Olovson et al. and to use starch as the gelling agent, taught by Calanchi et al. to be functionally equivalent to the gelling agents taught and used by Olovson et al. If the solutions prepared by Olovson et al. do not meet the particles size limitations of the instant claims, it also would be obvious to prepare particles with a diameter of 250 μm to 750 μm, taught by Calanchi et al. to reduce lump formation while not increasing the time necessary to prepare a solution of the appropriate viscosity.

10. Claims 1 – 5, 8 – 12 and 15 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olovson et al. as applied to claims 1 – 5, 8 – 9, 12, 13 and 15 – 18 above, and further in view of Mulchandani et al. (US 5,108,767).

Olovson et al. discloses aqueous compositions of enteric coated proton pump inhibitor particles, a gelling agent and optional flavoring components for the treatment of gastric disorders in patients. After mixing with water, the composition is administered by syringe. The administration of anti-ulcer compounds via oral or naso-gastric tubes can be used, although it requires trained personnel (p 1, ln 28 – 31).

Olovson et al. does not disclose the diameter of the feeding tube used.

Mulchandani et al. discloses a product that is drunk or administered by feeding tube and therefore should not have a viscosity of greater than 120 or 130 cps (centipoise; col 15, ln 18 – 21). This viscosity will allow for the composition to be administered using a size 8 or larger French (CH or Cherrier) tube and pump administration, or a size 10 French or larger tube when the preparation is administered by gravity.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to administered the multi-particulate enteric coated proton pump inhibitor composition using a feeding tube as taught by Olovson et al. with a feeding tube size of 8 or 10 or larger, as taught by Mulchandani et al. Additionally, if the viscosity of the formulations prepared by Olovson et al. does not meet the limitation on the claims, it would have been obvious to optimize the viscosity based on the method by which the formulation was to be administered and the size of the tube through which the

preparation was to be administered (e.g., syringe, gravity-fed feeding tube or pump-fed feeding tube).

11. Claims 1 – 5, 8 – 9, 12, 13 and 15 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olovson et al. as applied to claims 1 – 5, 8 – 9, 12, 13 and 15 – 18 above, and further in view of Cullen et al. (US 2002/0064555).

Olovson et al. discloses aqueous compositions of enteric coated proton pump inhibitor particles, a gelling agent and optional flavoring components for the treatment of gastric disorders in patients.

The dosages of the active ingredients in the examples (600 or 1200 mg) are much higher than those recited in claim 13.

Cullen et al. discloses dosages of various proton pump inhibitors. For examples, the dosage form can contain 20 mg of omeprazole (¶ [0045]) or 30 mg of lansoprazole (¶ [0055]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare the proton pump inhibitor composition administered for the treatment of gastric disorder as taught by Olovson et al. and to use a dosage of 20 or 30 mg, taught by Cullen et al. as suitable dosages for these ingredients. The amount of active ingredient present in the dosage form can be based on the specific active ingredient being used, the mass of the patient, the severity of the condition of the patient and the dosing schedule (once or multiple times per day). Optimization of

parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NMW

/Jake M. Vu/
Art Unit 1618